REMARKS

Claims 1-17 are pending in the present applications. Many of the claims have been amended to address § 112 rejections, claim objections, and to further clarify the recited claim language.

Applicant has carefully studied the outstanding Office Action. The present Response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of this application are respectfully requested. No new matter has been added by any of the amendments to the specification. Applicant respectfully requests reconsideration and withdrawal of the Examiner's rejections in view of the foregoing amendments and following remarks.

SPECIFICATION

The specification has been amended to remove Dr. Michael Blue as an inventor. The Declaration and Power of Attorney acknowledges that Mr. Oneal and Mr. White are the sole inventors of the method and composition claimed herein. Pursuant to 35 C.F.R. § 1.48(f) the submission of the Executed Oath and Declaration showing two inventors appears to have been sufficient to correct the inventorship of the pending application. No further action is believed necessary on this matter.

CLAIM OBJECTIONS

Claims 8 and 15 have been amended to address the Markush groups. Specifically, the claims have been amended such that the language "selected from the group consisting of" is recited.

CLAIM REJECTIONS – 35 U.S.C. § 112

The Examiner has rejected claims 1-14 and 17 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particular point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (and Claim 8)

With respect to claim 1, the Examiner stated:

> Claim 1 is drawn to a method of maintaining urinary tract health in the face of an infection. It is not clear what applicants intend by this recitation. For the purpose of prosecution, the claim is examined as drawn to a method of treating urinary tract infection. A similar interpretation of claim 8 is also in order.

In response to the Examiner's rejection of Claim 1 and Claim 8, the Applicant has amended the preamble of claim 1 and 8 accordingly. The respective claims now recite "a method of treating a urinary tract infection." The Applicant does not believe that this claim amendment changes, in any way, the claimed invention and is made at the request of the Examiner to provide a more concise statement of the intended purpose of the invention.

Claim 5

With respect to claim 5, the Examiner stated:

> Claim 5 recites the term affect. It is not clear what applicants intend by this term.

In response to the Examiner's rejection of claim 5, the Applicant has amended claim 5 replacing "herbs that affect the urinary tract" with "herbs." As such, the new claim is slightly broader, but clear.

Claims 12-14 and 17

With respect to claims 12-14 and claim 17, the Examiner stated:

> Claims 12-14 and 17 recite the term equivalents. In the absence of a recitation of what the equivalents are the claims are rendered indefinite.

In response to the Examiner's rejection of claims 12-14 and 17, the Applicant has amended the aforementioned claims striking the language "and equivalents." While the amendment is made to overcome a rejection under 35 U.S.C. § 112, the Applicant emphasizes that the amendment in no way is intended to waive any claims for "equivalents" under the legal theory regarding infringement known as the "Doctrine of Equivalents" or any similar legal theory of infringement.

Claim 12

With respect to claim 12, the Examiner stated:

> Claim 12 contains the trademark/trade name Cratavin. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. § 112, second paragraph. See *Ex parte Simpson,* 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used to properly identify any particular material or product. A trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an active agent and, accordingly, the identification/description is indefinite.

The Applicant agrees with the Examiner that the use of the term Cratavin™ is not proper when used within the claim limitations as in claim 12. For this reason, the Applicant has amended the claim language, replacing "Cratavin" with "extract of Crataeva nurvala." The amended claim language better exemplifies the intended scope of the claim.

Generally speaking, the aforementioned amendments overcome all of the § 112 rejections of the Examiner. For this reason, claims 6-17, which are not subject to any other claim rejections, are now believed to be in condition for allowance. Claims 1-5 are no longer subject to any § 112 rejections nor are they believed to be subject to any § 103 rejections, as described subsequently.

CLAIM REJECTIONS – 35 U.S.C. § 103

The Examiner has rejected claims 1-5 under 35 U.S.C. § 103(a) as being unpatentable over Benedict et al, U.S. Patent No. 6,753,319, (hereafter, Benedict) in view of Carella et al, WIPO International Publication No. WO 97/29763, (hereafter Carella) and Iwahi et al, J. Med. Microbiol., 1982, 15(3), 303-316 (hereafter Iwahi). After stating the factual inquiries required by *Graham* in determining the obviousness of an invention under 35 U.S.C. §103(a), the Examiner stated:

Benedict et al teach that D-Mannose has been widely used for the treatment of urinary tract infections (col. 1, lines 27-29). However, Benedict et al do not teach administering a dosage of one to two teaspoons of D-mannose to a patient three times a day with meals for one to two weeks or until the symptoms subside or a dose that contains approximately 2 grams of mannose.

Carella et al teach the use of D-mannose in a composition for the promotion of a healthy environment in urogenial tracts and for treating urogenital disorders (page 2, lines 7-10 and 16-17; page 5, lines 15-16). Plant extracts (interpreted as herbs that affect urinary tract, as instantly claimed in claim 5) are also included in the composition (page 8, lines 23-27). The compositions can be administered as tablets, capsules (page 10, lines 7-10) and can contain 5 to about 75% per unit dose (page 6, lines 22-25). According to Carella additional ingredients and dosages can be readily ascertained using routine experimentation (page 14, lines 32-35). This means that the art recognizes that dosages can be varied or requency of administration adjusted till symptoms subside.

Iwahi et al teach that d-mannose is potent in inhibiting viral adhesion to the urinary tract (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer d-mannose containing other herbs to treat urinary tract infection and maintain urinary tract health since the use of mannose for the said treatment is seen to be taught in the prior art. One of ordinary skill in the art would be motivated to use d-mannose as the active agent since d-mannose is potent in preventing viral adhesions to the urinary tract as taught by Iwahi et al.

The Applicant believes that claims 1-5 are nonobvious under 35 U.S.C. § 103(a) over Benedict in view of Carella and Iwahi. The first inquiry under *Graham* is the determination of the scope and contents of the prior art. The Examiner states that Benedict, which is prior art with respect to the present application, teaches the use of D-Mannose for treatment of urinary tract infections. However, the Examiner admits that Benedict fails to teach "administering a dosage of one to two teaspoons of D-mannose to a patient three times a day with meals for one to two weeks or until the symptoms subside" (Claim 1) and Benedict fails to teach "a dose that contains approximately 2 grams of mannose" (Claim 10). The Examiner made no suggestion within the Office Action that Claim 10 was rejected on § 103 grounds nor does the Examiner discuss anywhere in Carella that discusses 2 grams of mannose.

Claim 1

Claim 1, as amended, recites that a dosage of one to two teaspoons of D-mannose is

administered to the patient three times a day with meals for a period of at least one week and not more than two weeks. While Benedict fails to teach the aforementioned limitation, Carella also fails to teach administering (1) one to two teaspoons of D-mannose (2) three times a day with meals (3) for a period of at least one week and not more than two weeks. Carella states:

> "Those skilled in the art will quickly realize other suitable ingredients, diluents and dosage forms (or readily ascertain such using routine experimentation) which may further be incorporated into the above compositions without departing from the scope and spirit of the present invention."

Although Carella could be interpreted so as to suggest a larger "dosage form" of one to two teaspoons of D-mannose under Carella's disclosure that "suitable ingredients" and "dosage forms" may be determined experimentally, Carella fails to disclose administering the D-mannose three times a day with meals nor does it disclose administering for a period of one to two weeks. This is outside the scope of "suitable ingredients, diluents and dosage forms" as disclosed in Carella. In fact, Carella teaches a composition for treating urogenital disorders, but does not teach or suggest the method of administration claimed by the present invention, namely multiple administrations per day with meals nor administration on a regular basis over a period of one to two weeks. Absent such a teaching in Carella, Benedict, or Iwahi, the Examiner has failed to make a *prima facie* case of obviousness.

As such, claim 1 of the present application is nonobvious over Benedict in view Carella and Iwahi. Accepting that claim 1 is patentable over 35 U.S.C. §§ 102 and 103, none of the claims dependent on claim 1 may be rejected under 35 U.S.C. §§ 102 and 103. As such, claims 1-7, as amended, are all in condition for allowance. However, for good measure, the following addresses other basis of rejection of the dependent claims.

Claims 2-3

The Examiner fails to distinctly point out in either Benedict or Carella any suggestion that D-mannose should be administered orally (claim 2), that D-mannose should be administered as a powder (claim 3). Carella teachs only tablets and capsules. Therefore, claims 2 and 3 are in condition for allowance and are not subject to a rejection under 35 U.S.C. § 103.

Claims 5-17

Carella fails to disclose:

The method of claim 1 (discussed previously) wherein the capsule containing botantical

extract (Claim 5)

The method of claim 5 (see immediately preceding statement) wherein the extract is selected from Crataeva nurvala, willow bark, or pollen extract (Claim 6)

The method of claim 1 wherein the D-mannose is administered in a capsule and wherein the capsule contains an extract of Crataeva nurvala, willow bark, and pollen extract. (Claim 7)

The methods of claims 8-14 are not shown within any of the cited references or combination thereof.

The compositions of claims 15-17 are not disclosed within any of the cited references or combination thereof

Absent any specific identification of the aforementioned elements being taught or suggested in Benedict, Carella, or Iwahi the aforementioned claims are nonobvious under 35 U.S.C. § 103. The Examiner has the burden of establishing a *prima facie* case of obviousness. A general statement that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to administer d-mannose containing other herbs … is seen to be taught in the prior art" does not establish a *prima facie* case of obviousness.

CONCLUSION

Applicant has fully responded to the Examiner's rejections. It is respectfully urged that the subject application is patentable over references cited by Examiner and is now in condition for allowance. Applicant requests consideration of the application and allowance of the claims. If there are any outstanding issues that the Examiner feels may be resolved by way of a telephone conference, the Examiner is cordially invited to contact David W. Carstens at 972.367.2001.

The Commissioner is hereby authorized to charge any additional payments that may be due for additional claims to Deposit Account 50-0392.

Respectfully submitted,

By: _____

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